States Army and for appointment to the grade indicated under title 10, U.S.C., section 3036:

To be major general

Brig. Gen. David H. Hicks, 1012

The following Army National Guard of the United States officer for appointment in the Reserve of the Army to the grade indicated under title 10, U.S.C., section 12203:

To be major general

Brig. Gen. Brian L. Tarbet, 0965

The following named officer for appointment in the United States Army to the grade indicated under title 10, U.S.C., section 624:

To be brigadier general

Chaplain (Col.) Jerome A. Haberek, 0306

NAVY

The following named officer for appointment in the United States Navy to the grade indicated while assigned to a position of importance and responsibility under title 10, U.S.C., section 601:

To be vice admiral

Rear Adm. Michael J. McCabe, 0987

The following named officer for appointment in the United States Naval Reserve to the grade indicated under title 10, U.S.C., section 12203:

To be rear admiral

Rear Adm. (lh) John P. Debbout, 9101

The following named officer for appointment in the United States Naval Reserve to the grade indicated under title 10, U.S.C., section 12203:

To be rear admiral (lower half)

Capt. Craig O. McDonald, 8124

ARMY

PN283 Army nominations (13) beginning CHARLES R BAILEY, and ending DAVID W SMARTT, which nominations were received by the Senate and appeared in the Congressional Record of January 29, 2003

FOREIGN SERVICE

PN356–1 Foreign Service nominations (23) beginning Anne H. Aarnes, and ending Edward W. Birgells, which nominations were received by the Senate and appeared in the Congressional Record of February 25, 2003

MARINE CORPS

PN637 Marine Corps nominations (871) beginning BENJAMIN T ACKISON, and ending ROBERT B. ZWAYER, which nominations were received by the Senate and appeared in the Congressional Record of May 14, 2003

NAVY

PN588 Navy nominations (39) beginning AMADO F. ABAYA, and ending SHANNON J. WELLS, which nominations were received by the Senate and appeared in the Congressional Record of May 1, 2003

NOMINATIONS DISCHARGED

Mr. FRIST. Mr. President, in executive session, I ask unanimous consent that the HELP Committee be discharged from further consideration of the following nominations for the National Science Board: Steven Beering, PN44; Ray Bowen, PN46; Elizabeth Hoffman, PN50. I further ask unanimous consent that the Senate proceed to their consideration, the nominations be confirmed, the motions to reconsider be laid upon the table, the President be immediately notified of the Senate's action, and the Senate resume legislative session.

The PRESIDENT pro tempore. Without objection, it is so ordered.

The nominations considered and confirmed are as follows:

NATIONAL SCIENCE BOARD

Steven C. Beering, of Indiana, to be a Member of the National Science Board, National Science Foundation, for the remainder of the term expiring May 10, 2004.

Ray M. Bowen, of Texas, to be a Member of the National Science Board, National Science Foundation, for a term expiring May 10, 2008.

Elizabeth Hoffman, of Colorado, to be a Member of the National Science Board, National Science Foundation, for a term expiring May 10, 2008.

LEGISLATIVE SESSION

The PRESIDENT pro tempore. Under the previous order, the Senate will return to legislative session.

ANIMAL DRUG USER FEE ACT OF 2003

Mr. FRIST. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of Calendar No. 104, S. 313.

The PRESIDENT pro tempore. The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (S. 313) to amend the Federal Food, Drug, and Cosmetic Act to establish a program of fees relating to animal drugs.

There being no objection, the Senate proceeded to consider the bill, which had been reported from the Committee on Health, Education, Labor, and Pensions, with amendments, as follows:

[Strike the parts shown in black brackets and insert the parts shown in italic.]

S. 313

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Animal Drug User Fee Act of 2003''.

SEC. 2. FINDINGS.

Congress finds as follows:

(1) Prompt approval of safe and effective new animal drugs is critical to the improvement of animal health and the public health.

(2) Animal health and the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for review of new animal drug applications.

(3) The fees authorized by this title will be dedicated toward expediting the animal drug development process and the review of new and supplemental animal drug applications and investigational animal drug submissions as set forth in the goals identified, for purposes of part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Energy and Commerce of the House of Representatives and the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate as set forth in the Congressional Record.

SEC. 3. FEES RELATING TO ANIMAL DRUGS.

Subchapter C of chapter VII of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 379f et seq.) is amended by adding at the end the following part:

[''PART 3—FEES RELATING TO ANIMAL DRUGS]

''PART 4—FEES RELATING TO ANIMAL DRUGS

[''SEC. 738. DEFINITIONS.

[''For purposes of this subchapter:**]**

''SEC. 739. AUTHORITY TO ASSESS AND USE ANIMAL DRUG FEES.

*(a)***]** *DEFINITIONS.—For purposes of this subchapter:*

''(1) The term 'animal drug application' means an application for approval of any new animal drug submitted under section 512(b)(1). Such term does not include either a new animal drug application submitted under section 512(b)(2) or a supplemental animal drug application.

''(2) The term 'supplemental animal drug application' means—

''(A) a request to the Secretary to approve a change in an animal drug application which has been approved; or

''(B) a request to the Secretary to approve a change to an application approved under section 512(c)(2) for which data with respect to safety or effectiveness are required.

''(3) The term 'animal drug product' means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an animal drug application or a supplemental animal drug application has been approved.

''(4) The term 'animal drug establishment' means a foreign or domestic place of business which is at one general physical location consisting of one or more buildings all of which are within 5 miles of each other, at which one or more animal drug products are manufactured in final dosage form.

''(5) The term 'investigational animal drug submission' means—

''(A) the filing of a claim for an investigational exemption under section 512(j) for a new animal drug intended to be the subject of an animal drug application or a supplemental animal drug application, or

''(B) the submission of information for the purpose of enabling the Secretary to evaluate the safety or effectiveness of an animal drug application or supplemental animal drug application in the event of their filing.

''(6) The term 'animal drug sponsor' means either an applicant named in an animal drug application, except for an approved application for which all subject products have been removed from listing under Section 510, or a person who has submitted an investigational animal drug submission that has not been terminated or otherwise rendered inactive by the Secretary.

''(7) The term 'final dosage form' means, with respect to an animal drug product, a finished dosage form which is approved for administration to an animal without substantial further manufacturing. Such term includes animal drug products intended for mixing in animal feeds.

''(8) The term 'process for the review of animal drug applications' means the following activities of the Secretary with respect to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions:

''(A) The activities necessary for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

''(B) The issuance of action letters which approve animal drug applications or supplemental animal drug applications or which set forth in detail the specific deficiencies in animal drug applications, supplemental animal drug applications, or investigational